SEALED

FILED
OCT 30 2013
CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY _____ DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

United States of America, and
State of Texas,
ex rel. Sergio Garcia

PLAINTIFFS

v.

Dr. Robert Moreno,
Cheryl Moreno,
William "Bill" Collins,
Accutrack Medical Claims Service, LLC,
El Paso Integrated Physicians Group, P.A.,
Dr. Mariano Palacios, and
Karla Porras

DEFENDANTS

SA13CV0992 XR

Civil Action No:_____

COMPLAINT FILED *IN CAMERA* AND UNDER SEAL

COMPLAINT OF RELATOR SERGIO GARCIA PURSUANT TO FEDERAL FALSE CLAIMS ACT AND TEXAS FALSE CLAIMS ACT

TRIAL BY JURY REQUESTED

Plaintiffs the United States of America and the State of Texas, by and through *qui tam* plaintiff relator Sergio Garcia, bring this action under 31 U.S.C. §§ 3729-3732 (the "False Claims Act" or the "Act") and Tex. Hum. Res. Code § 36.001 *et seq.* (the "Texas False Claims Act") to recover all damages, penalties, and other remedies established by these acts, and state as follows for its cause of action against Defendants:

I. Introduction

1. This is an action under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and the Texas False Claims Act, Tex. Hum. Res. Code § 36.001 *et seq.*, brought against Dr. Robert Moreno, Cheryl Moreno, William "Bill" Collins, Dr. Mariano Palacios, El Paso Integrated Physicians Group, P.A. ("Physicians Group"), Karla Porras, and Accutrack Medical Claims Service, LLC for presenting false claims to Medicare, Medicaid and other government agencies. Defendants fraudulently made claims for payment and billed Medicare, Medicaid, and TRICARE for (1) pharmaceutical drugs that were illegally pooled, diluted, or never administered to patients; (2) drugs illegally imported and for the use, administration, and prescription of such illegal drugs; and (3) medical services that were up-coded to conceal that the services provided were of lesser qualities and quantities than those claimed for reimbursement.

2. From a time unknown, but no later than January of 2005 through the present, the federal and state governments, through Medicare and Medicaid reimbursements, paid Defendants for claims for patient services and drugs that were false.

3. Defendants' false claims for reimbursement for medical services and drugs provided to patients primarily involve the in-office infusion of the drug Remicade (the brand name for Infliximab), billed to the government by Dr. Moreno and/or Physicians Group.

4. Medicare and Medicaid reimburses only those medical providers who are deemed qualified to receive reimbursement for covered medical services actually furnished to a patient. 42 CFR § 424.5(a). Medicare and Medicaid only make payments to providers for medical services when those providers have complied with the respective federal health care program's rules and policies, including requirements under federal or state laws and regulations.

5. Defendants made false claims by falsely billing, causing to be billed, and conspiring to bill Medicare and Medicaid for four schemes: (1) billing for pooled residual amounts of Remicade in violation of Medicare and Medicaid rules and policies; (2) billing for more Remicade than Defendants purchased, either by diluting, under-dosing, or never administering some doses to patients; (3) billing for illegally purchased and imported pharmaceuticals from Canada and/or other foreign countries and for prescribing and administering those drugs to patients; and (4) billing for physicians' services in amounts that exceeded the quality and quantity of services actually provided.

6. Plaintiff's claims against Defendants:

a. **Billing for pooled residual amounts of Remicade in violation of Medicare and Medicaid rules and policies**: Defendants would systematically cause previously entered vials of Remicade to be taken home by Physicians Group staff, pooled, and returned for administration to patients.

i. Because Remicade dosage is specific to a patient's weight and the number of milligrams in a vial is often different from the exact patient dosage, it is common to have a remainder, or residual, amount of Remicade after an infusion.

ii. Medicare and Medicaid billing rules allow providers to bill for the residual amount of Remicade as wastage so long as the amount is discarded and not administered to another patient.

iii. Additionally, because Remicade does not contain antibacterial preservatives, the remaining amounts cannot be re-entered or stored for risk of product contamination and threat to patient health.

iv. Defendants never billed Medicare or Medicaid for wastage. Instead, Defendants would cause Remicade residuals to be taken home, combined with other residual amounts or pooled, and administered to patients as if they were new vials of Remicade. Defendants would then improperly bill Medicare and Medicaid for these infusions.

b. **Billing for more Remicade than Defendants purchased**: Defendants were either diluting or never administering vials of Remicade to patients who required the drug:

i. From 2005 until 2009, Physicians Group sold an estimated 181,468 units of Remicade, while records show only 105,840 units were purchased—a 71% increase from purchase to sale.

ii. Pooling of residual wastage would only explain at most a 33% increase from purchase to sale, not a 71% increase.

iii. Therefore, Medicare and Medicaid fraud is the only explanation for the difference between (1) the number of units purchased, (2) the number of units billed, and (3) the number of residual units estimated to have been pooled.

c. **Billing for pharmaceuticals imported from Canada or other foreign countries**:

i. Beginning in mid-2009, Dr. Moreno began ordering and receiving Synvisc from Canada. Synvisc is a drug used to treat joint arthritis or joint disfunction.

ii. By August of 2010, Dr. Moreno was ordering and receiving Reclast from Canada. Reclast is a drug used to treat osteoporosis and other deceases of the bone which Professional Group prescribed and administered to its patients.

d. **Billing for physician's services in amounts that exceeded the quality and quantity of services actually provided:** Dr. Mariano Palacios upcoded services and performed unnecessary procedures.

II. Jurisdiction and Venue

7. This is an action to recover damages and civil penalties arising out of false claims presented by Defendants to the United States and the State of Texas. The action arises under the provisions of Title 31 U.S.C. § 3729, *et seq.*, the False Claims Act, which provides that the United States shall have exclusive jurisdiction of actions brought under the Act.

8. Subject matter jurisdiction in this Court is therefore based upon 28 U.S.C. § 1331 and 31 U.S.C. § 3732.

9. Subject matter jurisdiction of the actions brought by and on behalf of the State of Texas are based on 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367.

10. Venue is proper in this Court by virtue of 28 U.S.C. § 1391 and 31 U.S.C. § 3732(a) of the False Claims Act as the wrongful acts alleged occurred largely in this District and Defendants reside and conduct business in this District.

11. Defendants' conduct had a material effect on the Governments' decisions to pay the claims presented by Defendants. Had the federal government and the State of Texas known that Defendants were diluting medication; improperly repackaging and reusing medication; failing to dispose of overages; illegally importing drugs administered to patients; up-coding, exaggerating, and inflating descriptions of medical services on claims; and falsifying certifications and claims; the federal government and the State of Texas would not have paid the reimbursements claimed.

12. Defendants' fraudulent conduct described in this Complaint is ongoing.

13. Under the False Claims Act, this Complaint is to be filed *in camera* and remain under seal for a period of at least sixty (60) days and shall not be served on Defendants until the Court so orders. The United States may elect to intervene and proceed with the action within sixty days after it receives the complaint, material evidence, and any other necessary information.

14. As required by the Act, 31 U.S.C. § 3730(b)(2), Relator has provided to the Attorney General of the United States and to the United States Attorney for the Western District of Texas, simultaneously with the filing of this Complaint, a confidential, privileged and work product statement of substantially all material evidence and information related to this Complaint. It was provided to the government pursuant to a joint prosecutorial and common interest privilege.

III. Parties

A. Relator Sergio Garcia

15. Plaintiff/Relator Sergio Garcia ("Mr. Garcia" or "Relator Garcia") is a resident of El Paso, Texas.

16. Mr. Garcia was employed by the Defendant El Paso Integrated Physicians Group ("Physicians Group") from October 1999 through 2010, managing and supervising medical billing, accounting, and ordering of supplies and medications. For most of this time, Relator Garcia was the Practice Administrator until, in 2009, his title changed to Assistant Administrator, but his functions remained essentially unchanged.

17. Mr. Garcia oversaw billing records, including computations of charges for services rendered. Mr. Garcia had access to refrigerated and secured medications as part of his duty to

order medications and supplies. Mr. Garcia compiled final summaries of income and cost for transmission to Physicians Group's accountant for tax preparation.

18. Relator Garcia is an original source of the False Claims Act violations alleged in this Complaint, and those allegations are not based on publically disclosed information.

B. Plaintiffs the United States of America and the State of Texas

19. The United States of America is a Plaintiff in this action. At all times material to this Complaint, the Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS" or "Medicare") were agencies and instrumentalities of the United States, and their activities, operations, and contracts were paid from federal funds.

20. The State of Texas is a Plaintiff in this action. At all times material to this Complaint, the Texas Medicaid Program ("Medicaid") was an agency and instrumentality of the State of Texas, paid jointly by federal and state funds.

C. Defendant Dr. Robert Moreno

21. Defendant Dr. Robert Moreno ("Dr. Moreno") is a physician licensed to practice medicine in Texas. For all times relevant to this Complaint, Dr. Moreno was a provider for Medicare and Medicaid.

22. Dr. Robert Moreno is a practitioner for Physicians Group specializing in internal medicine and rheumatology. Dr. Moreno is the majority owner of Physicians Group and, at all relevant times, was and is the person in control of Physician Group's practice including, but not limited to, all financial, accounting, business, and personnel matters.

D. Defendant Cheryl Moreno

23. Cheryl Moreno is the wife of Dr. Moreno and an owner of Accutrack Claims Service, LLC ("Accutrack"). Mrs. Moreno works closely with her husband to operate and control Physicians Group 's medical practice.

24. Mrs. Moreno, a trained accountant who answers only to Dr. Moreno, controls all of Physicians Group 's billing for Remicade, Reclast, and Orencia.

E. Defendant El Paso Integrated Physicians Group, P.A. ("Physicians Group")

25. Defendant El Paso Integrated Physicians Group, P.A. ("Physicians Group") provides medical services through its physician and majority owner, Dr. Moreno.

26. For all times relevant to this Complaint, Physicians Group was a provider for Medicare and Medicaid.

27. Physicians Group is a privately owned outpatient clinic with Dr. Robert Moreno having majority (51%) ownership.

28. Physicians Group has practitioners in several areas, including rheumatology and internal medicine and operates an on-site infusion center.

F. Defendant Accutrack Medical Claims Services, LLC ("Accutrack")

29. Accutrack Medical Claims Services, LLC performs medical coding and billing for Physicians Group.

G. Defendant William ("Bill") Collins

30. Defendant William ("Bill") Collins works for Physicians Group and for Accutrack and owns 50% of Accutrack.

31. Mr. Collins works closely with Dr. Moreno and has conspired and aided Dr. Moreno in committing the illegal acts that form the basis of this Complaint, in concealing and covering-up those acts, and in violating the False Claims Act.

H. Defendant Mariano Palacios, M.D.

32. Defendant Dr. Mariano Palacios ("Dr. Palacios") is a physician licensed to practice medicine in Texas. For all times relevant to this Complaint, Dr. Palacios was a provider for Medicare and Medicaid.

33. Dr. Palacios worked for Physicians Group at all relevant times herein.

I. Defendant Karla Porras

34. Karla Porras is the primary infusion nurse for Physicians Group.

35. She is responsible for administering intravenous arthritis medications in the in-house infusion center as ordered by Physician Group physicians.

36. As discussed below, under the Morenos' instructions, and with their knowledge, Karla Porras takes the Remicade home and combines and/or dilutes it.

IV. The Legal Background to the False Claims

A. Medicare

37. The Medicare program, established in 1965 by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, consists of two parts. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care, including SNFs and long-term care facilities. Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation, physician services, laboratory services, outpatient therapy,

diagnostic services, radiology services, ambulance services, portable x-rays, and durable medical equipment. These payments are fixed by the Medicare Fee Schedule.

38. Under the authority of the Social Security Act, the Secretary of HHS administers the Medicare Program through Centers of Medicare and Medicaid Services (CMS). CMS contracts with private insurance companies to administer the processing of claims. Part A reimbursement is processed through Fiscal Intermediaries. Part B reimbursement is processed through Medicare Carriers.

39. CMS enters into provider agreements with providers and suppliers to establish eligibility to participate in the Medicare Program. In order to be eligible for payment under the program, providers and suppliers must submit applications and be accepted by the programs as participating providers. In order to be reimbursed through the program, participating providers must certify to the government that they understand that payment of claims is conditioned on the claim and the underlying transaction complying with all applicable laws, regulations and program instructions.

40. In order for a physician to obtain payment from CMS, a physician as a provider/supplier must apply for authorization to participate in the Medicare and Medicaid programs. A participating supplier means a supplier that has an agreement with CMS to participate in Part B of Medicare in effect on the date of the service. 42 C.F.R. § 202. A participating provider is one who is either (in the fee-for-service program), any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency, or (for the managed care program) any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the state in which it delivers the services. 42 C.F.R. § 203.

41. To be eligible for payment under the state Medicaid programs, providers and suppliers must apply for and receive participating status and certify that they understand that payment of claims are conditioned on the claim and underlying transaction complying with laws, regulations and program instructions.

42. Every provider and supplier, including Defendants herein, is required to sign a provider agreement (CMS-855I) certifying that:

> *I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in § 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor.*
> *I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.*

43. Defendants expressly certified compliance with the provisions of Medicare and other applicable laws, regulations, and provider instructions when they signed provider applications and cost reports and submitted them to the U.S. government for reimbursement.

44. These documents that contain Defendants' certifications of compliance were submitted to the government as a condition to receiving Medicare and Medicaid reimbursements.

45. By virtue of Defendants' execution of Provider Applications, Defendants knew or should have known of Medicare's requirements and the need to conform to these statutory requirements as a condition to receiving reimbursements from the government.

B. Medicaid

46. Medicaid is a health care benefit program as defined by Title XVIII, United States Code, § 24(b). The Texas Medicaid Assistance Program (Medicaid) was established on September 1, 1967, under the provisions of Title XIX of the Federal Social Security Act and Chapter 32 of the Texas Human Resources Code.

47. The State of Texas and the United States share the cost of funding the Texas Medicaid Program. The Texas Health and Human Services Commission's (HHSC) is responsible for administering the Title XIX Medicaid Program in Texas. Administration of the program is accomplished through contracts and agreements with medical providers. The Texas Medicaid & Heathcare Partnership (TMHP) administers the payments of claims.

48. By signing a Texas Medicaid Provider Agreement and submitting Medicaid claims, each enrolled provider agrees to abide by the policies, procedures and regulations of Medicaid and the information and instructions in manuals, bulletins, and other instructional materials furnished to the provider. Medicaid medical service rules are described under the Texas Administrative Code ("TAC") Part 1, Chapter 33. Additionally, all providers are required to read and comply with § 1 of the Texas Medicaid Providers Procedures Manual, and providers are required to read, comply with and bill Medicaid in accordance with the Texas Medicaid Providers Procedure Manual, which sets out specific provisions pertaining to billing and medical care. Providers must comply with all requirements specific to Texas Medicaid, and it is a violation of Texas Medicaid Rules for a provider to fail to provide health care services or items to Medicaid clients in accordance with accepted medical community standards and standards that govern occupations, as set out in TAC § 371.1617(a)(6)(A).

V. Remicade Fraud

A. Remicaide Pooling and Reuse

i. Remicade Background

49. Remicade is the brand name for the pharmaceutical drug *infliximab*. It is manufactured and distributed in the United States by Janssen Biotech, Inc.

50. Remicade is a monoclonal antibody used to treat autoimmune diseases, such as rheumatoid arthritis, Crohn's disease, psoriasis, psoriatic arthritis, and ulcerative colitis. With these diseases, the body mistakenly perceives healthy cells as pathogens and attacks itself.

51. Remicade suppresses patients' immune systems.

52. Due in part to its impact on the immune system, one of Remicade's severe side effects is heightened susceptibility to infections caused by fungi or bacteria. Significantly, the manufacturer's "IMPORTANT SAFETY INFORMATION" (all caps original) on its label specifically warns for this: "Patients treated with Remicade (infliximab) are at increased risk for developing serious infection that may lead to hospitalization or death." It goes on to identify reported infections including active tuberculosis, "invasive fungal infections," and "bacterial, viral, and other infections due to opportunistic pathogens."

53. Remicade is distributed in single-dose/use glass vials containing 100 mg of the medication in powder form. It is reconstituted with 10 milliliters (ml) of sterile water, resulting in a concentration of 10mg/ml vials containing 10 units, each unit being 10mg of the antibody. The appropriate dosage for a patient is drawn from the vial(s) and then further diluted with a saline solution, reconstituted, or mixed into an intravenous ("IV") solution before it is administered via IV drip to the patient.

54. Remicade is distributed in single-dose/use vials and, as such, the vials do *not* contain antibacterial preservatives.

55. Once a single-dose/use vial is entered, it should never and cannot legally be re-entered or stored due to the extremely high risk of product contamination and the potential for patient infection.

56. CMS recently instructed its state agency directors that healthcare facilities that reuse single-dose/single-use vials for multiple patients must be cited for noncompliance.

57. Similarly, the Federal Food, Drug and Cosmetic Act ("FFDCA") prohibits the adulteration or misbranding of any drug in interstate commerce. 21 U.S.C. § 331(b).[1]

58. The risk of infection is especially concerning with Remicade because the drug acts as an immunosuppressant in patients, causing them generally to be at a much higher risk of infection.

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1 21 U.S.C. § 331 - Prohibited acts
The following acts and the causing thereof are prohibited:
(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.
(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
. . .
(i) . . .
(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.
. . .
(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

To avoid contamination and possible patient infection, the manufacturer instructs that any remaining medication in the Remicade vial not administered to the patient must be discarded and documented as such.

59. Remicade is covered by Medicare Part B as an injectable administered directly by a health care provider.[2] *See* 42 C.F.R. § 405.517.

60. Because a single-dose vial of Remicade cannot be re-used, Medicare reimburses for the entire vial, but the unused portion must be reported as such.

> When a physician, hospital or other provider or supplier must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.
>
> ...
>
> This [JW] modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. For example, a single use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units may be billed on another line by using the JW modifier. Both line items would be processed for payment.
>
> Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, 40 - Discarded

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2 Medicare Part B does not generally cover the cost of prescription drugs that a Medicare beneficiary *self-administers*, for example by swallowing the drug in liquid or pill form. However, Part B does cover some drugs, including those such as Remicade that must be administered by a healthcare provider.

Part B reimburses medical providers 80% of the allowable amount. The remaining 20%, the "co-payment amount," is paid by the beneficiary. The allowed amount would be based upon the lower of the actual charge on the Medicare claim form or 95% of AWP. 42 C.F.R. § 405.517. However, where a healthcare provider elects to accept payment directly from the Medicare program, it may not charge the individual enrollee more than 20 percent of the reasonable cost of the Covered Drug or biological. 42 U.S.C. §§ 1395(j)-1395(w-4).

Drugs and Biologicals. [3]

61. For example, the recommended dosing for Remicade in an average rheumatoid arthritis patient is 3 mg per kilogram of patient's weight. For a patient weighing 150 pounds (68 kg), the dose would be approximately 204 mg. The required 204 mg dose would necessitate the use of three 100 mg vials, with a wastage of 96 mg. The wastage should be reported and billed to Medicare.

62. Given that the residual amount cannot be re-entered, stored, or pooled for later use, a Remicade infusion center must routinely discard residual amounts.

63. Since billing for wastage is the only way that an infusion center could be compensated for the unused portion, infusion centers bill Medicare for Remicade wastage or lose money administering the drug. But Defendants do not bill for Remicade wastage.

64. Most Remicade infusion clinics have low profit margins. This is particularly true since 2005 when the Center for Medicare and Medicaid Services ("CMS") changed their reimbursement for infliximab (Remicade) from $77 per gram in 2003 to $57 per gram.

65. In an e-mail from Bill Collins to Mr. Garcia regarding Physicians Group's January 2010 Remicade Profitability Estimate, Collins calculated that Physicians Group loses money administering Remicade.

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3 http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf Last checked 8/24/13.

66. Mr. Collins was aware of the challenges of earning a profit administering Remicade through *legitimate* means.

ii. Double Billing -- Introduction

67. Physician Group reports and bills for more Remicade than the amount it purchases.

68. From 2005 until 2009, Physicians Group sold an estimated 181,468 units of Remicade, while records show only 105,840 units were purchased—a 71% increase from purchase to sale.

69. In 2009, for example, Defendants purchased 18,743 units and sold 38,890 units, twice the amount purchased. Many of these units were billed to Medicare.

70. Physicians Group inflated their billing of Remicade to Medicare from at least 2005 to 2009. Yet, it did not bill for or report any Remicade wastage to Medicare.

71. Defendants filed or caused the filing of false claims when Physicians Group double-billed Medicare by billing for Remicade paid for by other patients' health care benefit programs and by billing for contaminated Remicade.

72. The inflated billing was due, in part, to the dilution and to the pooling of the unused portion of single-use vials by the nurse who infused the drug, Karla Porras.

iii. Double Billing by Pooling and Reusing Single-dose Vials

73. Nurse Karla Porras was "pooling" Remicade medication at her home with the instructions and knowledge of Defendants Dr. and Mrs. Moreno, and Bill Collins.

74. "Pooling" is a form of adulteration by combining and reusing left-over medication to make one vial of ten ml.

75. Dr. Moreno would say such things as "she [Karla Porras] saved us 'x' number of vials," (for example, 50 vials) and then convert that savings into a dollar value.

76. In approximately 2005 or 2006, representatives of Centercor, the manufacturer of Remicade, asked another employee, Rosa Saenz, for permission to see Physician Group's records reflecting patient numbers. They were inquiring about why, as the practice grew, the amount of Remicade being ordered was not increasing.

77. Dr. Moreno instructed that neither Rosa nor anyone else was to share any records or information or have any discussions with anyone from Centercor.

iv. Pooling Violates the FCA

78. Administering drugs from one single-dose vial (SDV) to multiple patients is not an acceptable practice under CMS infection control regulations. Medicare providers are subject to Medicare health and safety standards and must comply with infection control requirements. *See e.g.*, 42 C.F.R. § 416.51 (ASCs), 42 C.F.R. § 482.42 (hospitals).[4]

79. This "existing policy" was recently confirmed: "CMS is maintaining our existing policy that reuse of a SDV for multiple patients or residents is not acceptable."[5]

80. Of course, items or services that are "not acceptable" to CMS are intrinsically not "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A).

81. Similarly, pharmaceutical manufacturers are prohibited from salvaging drug products. 21 C.F.R. § 211.208.

82. A provider or supplier also has actual or constructive knowledge of non-covered items or services based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or

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4 http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf Last checked 8/24/13.

5 http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-35.pdf at p. 5

other written guides or directives from [Medicare contractors]" and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." 42 C.F.R. §§ 411.406(e)(1)and (e)(3).

B. Remicade Dilution

i. Background

83. Pooling residual wastage does not explain the entire fraud. Given that the ratio between the amount of Remicade purchased by the clinic and the amount billed to Medicare is [1 : 1.71], and the ratio between usage and wastage for an average patient is [2.04 : .96], the pooling of the residual amounts alone does not bridge the gap between the amount of Remicade purchased by Physicians Group and the amount billed to Medicare.

84. To put it another way, pooling of residual wastage would only explain at most a 33% increase from purchase to sale, not the 71% increase identified in Physician Group's purchase and sales ratio from 2005 to 2009.

85. Defendants committed another fraud by either billing for infusions using vials that did not have the appropriate amount of medication, pooling, and/or billing for infusions that were not actually given.

86. Dr. Moreno hid the discrepancy in the amount of Remicade purchased and the amount sold from Physician Group physicians and employees by giving his wife exclusive control over Remicade billing.

87. When Mrs. Moreno would go out of town for several days or weeks, the infusion billing would fall behind, thereby lowering the practice's cash flow.

88. When Mr. Garcia suggested that this delay in reimbursement revenue could be corrected by having someone else do the infusion billing, Dr. Moreno, normally very sensitive about prompt billing, would say, "Just wait until she comes back."

89. Dr. Moreno knew the dangers that pooling and storing single-dose medications could have because he, along with Physicians Group's staff, participated in training offered by Remicade's manufacturer, Janssen Biotech, Inc., f/k/a Centocor Biotech, Inc.

90. This training included instruction to discard the unused portion of the reconstituted vial. The staff was given specific instructions to immediately discard residual amounts of the Remicade because the drug contained no antibacterial additives or preservatives and using stored residual medication risked patient harm.

91. Dr. Moreno knew that there was a billing code for wastage to get reimbursed for the unused remainder. But this billing code was never used.

ii. Diluting Violates the FCA

92. Defendants sold more Remicade than they purchased.

93. "No payment is made for amounts of product in excess of that reflected on the FDA-approved label." 42 C.F.R.§ 414.904 (a)(3)(iii).

94. Only under limited circumstances, does the FDA or CMS permit repackaging of single-dose vials.[6]

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6 http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-35.pdf

95. Similarly, the CDC views this as a risky practice to be avoided.[7]

VI. Canadian Drug Purchases

A. Canadian Drug Purchases -- Background

96. Physicians Group administers several medications in the infusion center. These include Synvisc, used for treating knee pain caused by osteoarthritis; Orencia, used for treating rheumatoid arthritis; and Reclast used for preventing or treating osteoporosis (brittle bones).

97. The group began patient infusion with these drugs on January 9, 2009. Initial purchases were from legitimate United States Food and Drug Administration-approved venders.

98. In October of 2009, Mr. Garcia first became aware that pharmaceuticals were being ordered from Canadian suppliers when he saw and paid a credit card debit from Canadian Health Solutions for Synvisc.

99. Payments for drug purchases from Canada were made by checks, various credit cards, and perhaps wire transfers.

100. Reclast was first ordered from Canada by Dr. Moreno himself in August 2010 and verified by invoice on August 31, 2010.

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7 The CDC also warns on its website: *Protect Patients Against Preventable Harm from Improper Use of Single–Dose/Single–Use Vials:*

> In times of critical need, contents from unopened single–dose/single–use vials can be repackaged for multiple patients. However, this should only be performed by qualified healthcare personnel in accordance with standards in United States Pharmacopeia External Web Site Icon General Chapter ‹797› Pharmaceutical Compounding — Sterile Preparations. Following the USP standards is imperative, as medication contamination and patient harm can occur when repackaging (e.g. splitting doses) is not done properly.
> http://www.cdc.gov/injectionsafety/CDCposition-SingleUseVial.html last checked 8/24/13

101. Around 2007, Christina Queenie, a drug representative for Reclast (Novartis) came to the office and spoke with Rosa Saenz to inquire about the number of patients being administered Reclast.

102. Ms. Queenie told Ms. Saenz that her company records indicated Physicians Group was not buying enough Reclast for the number of patients being treated and, if drugs were being ordered from Canada, such purchases were illegal.

103. Ms. Saenz brought this information to Mr. Garcia who, in turn, reported this to Dr. Moreno.

104. The pharmaceutical representative also met with Dr. Moreno to show him articles and newspaper clippings showing that such importations were illegal.

105. Because he was confronted with the subject, Dr. Moreno instructed Mr. Garcia to investigate the legality of such Canadian purchases. A few minutes on the internet confirmed for Mr. Garcia that such purchases were illegal, an answer unacceptable to Dr. Moreno.

106. Dr. Moreno continued to purchase Canadian drugs. Those purchases included Remicade, Reclast, Synvisc and Orencia because Mr. Garcia saw invoices and payments to Canadian pharmacies for these drugs.

B. Unauthorized Importation Violates the FCA

107. Unauthorized importation is prohibited under 21 U.S.C. § 331 - Prohibited acts:

> (t) The importation of a drug in violation of section 381 (d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353 (c) of this title . . . or the failure to otherwise comply with the requirements of section 353 (d) of this title, or the distribution of drugs in violation of section 353 (e) of this title or the

failure to otherwise comply with the requirements of section 353 (e) of this title.

108. There are few exceptions to the ban on imports and re-imports, none of which apply here.[8]

109. Import ban violations may result in criminal and civil liability.[9] 21 U.S.C. § 331.

VII. Upcoding and Unnecessary Procedures by Dr. Palacios

110. Each procedure performed by a doctor or other healthcare provider has a code attached to it that allows them to bill insurance, Medicaid or Medicare, or other payor sources. That code is called a CPT code (current procedural terminology). When the physician sends in a bill for reimbursement, that CPT code determines how much he or she will get paid. Of course, different

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8 For example, under certain *specific* circumstances, imports and re-imports are allowed by manufacturer, 21 USC § 381(d)(1); consumers for personal use, 21 U.S.C. § 384(j)(2)(A), and pharmacists and wholesalers, 21 U.S.C. § 384(b).

9 21 USC § 333 – "Penalties" provides at section (b):

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a) of this section, any person who violates section 331 (t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

. . .

(D) knowingly distributing drugs in violation of section 353 (e)(2)(A) of this title,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

codes allow them to bill for higher or lower amounts, usually based on complexity and time spent with the patient.

111. Upcoding, then, refers to the practice of assigning a code that commands more money than the proper code would pay. For example, the doctor sees the patient for a quick check-up. The CPT code used for billing a check-up might mean the reimbursement would be $50. Instead, the physician assigns it the CPT code for an expanded check-up, which means reimbursement would be paid at $100.

112. Dr. Palacios routinely worked approximately six hours a day but consistently billed for nine to eleven hours of time when all the CPT codes used are totaled by time.

113. Dr. Palacios also refers many of his patients for unnecessary ancillary services.

114. For example, on October 22, 2009, Dr. Palacios ordered twelve patients to undergo somatosensory evoked potential (SSEP) testing after all twelve patients were given a diagnosis of dizziness.

115. SSEP is an evoked potential caused by a physical stimulus (usually a small electric pulse). Electrodes positioned over particular areas of the body record responses of the SSEP, these are then observed as a reading on an electroencephalogram (EEG). A doctor may recommend a SSEP test if the patient has been experiencing feelings of numbness or weakness in their arms or legs that may be due to problems affecting the somatosensory nerve pathway.

116. Each of the twelve patients on that one day that Dr. Palacios ordered the testing had a diagnosis of dizziness and not any neurological complaint. Dizziness is not a medical indication for use of this test.

117. Dr. Palacios's fraudulent course of conduct was made or carried out with the requisite scienter; based on material, false statements; and that caused the government to pay out money or to forfeit moneys.

VIII. Causes of Action

A. Count I: False Claims, 31 U.S.C. §§ 3729(a)(1)

The preceding paragraphs of this Complaint are re-alleged as though fully set forth herein.

118. From at least January of 2005 through the present, Defendants knowingly presented, or caused others to present, to an officer, employee or agent of the United States Government false or fraudulent claims for payment or approval in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733.

119. Defendants submitted claims, or caused claims to be submitted to the Center for Medicare and Medicaid Services (CMS).

120. As used herein, the work "knowingly" means that a person, with respect to information (a) has actual knowledge of the information, (b) acts in deliberate ignorance of the truth or falsity of information, or (c) acts in reckless disregard of the truth or falsity of the information.

121. Because of Defendants ' acts, the Government sustained damages.

B. Count II: Conspiracy to Submit False Claims, 21 U.S.C. § 3729(a)(3)

Paragraphs 1 through 117 of this Complaint are re-alleged as though fully set forth herein.

122. From at least January of 2005 through the present, Defendants knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims allowed or paid in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733.

123. Defendants conspired to defraud the Government by having a false or fraudulent claim allowed or paid in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733.

124. Because of Defendants' acts, the Government sustained damages.

C. Count III: Violation of Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §36.001 *et seq.*

Paragraphs 1 through 117 of this Complaint are re-alleged as fully set forth herein.

125. This is a civil action brought by Relator Garcia on behalf of the State of Texas against Defendants under the Texas Medicaid Fraud Prevention Act. Hum Res. Code Ann. § 36.101(a).

126. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and probably are continuing to make or causing to be made, false statements or misrepresentations of material fact that permit Defendants to receive benefits or payments that were not authorized or were greater than the benefit or payment authorized under the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

127. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed and may still be concealing or failing to disclose, or causing to be concealed or not disclosed, information that permitted Defendants to receive benefits or payments that were not authorized or were greater than the benefit or payment authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

128. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).

129. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and may still be making, claims under the Medicaid program for services or products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

130. The State of Texas, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for claims for services and products for recipients of Medicaid that it would not have paid had it known of such falsity.

131. As a result of Defendants' actions, as set forth above, the State of Texas and/or its political subdivisions have been, and may continue to be severely damaged.

Wherefore, Relator prays for judgment against Defendants as follows:

1. That Defendants be ordered to cease and desist from submitting or causing to be submitted any more false claims, or further violating 31 U.S.C. § 3729 *et seq.* and Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

2. That a judgment be entered in favor of Relator, the United States, and the State of Texas against Defendants in the amount of each and every false or fraudulent claim multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not

less than five thousand dollars ($5,000) or more than eleven thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery.

3. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and Tex. Hum. Res. Code Ann. § 36.110, including reasonable attorneys' fees and litigation cost.

4. That judgment be entered in Relators ' favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tex. Hum. Res. Code Ann. § 36.052(a), multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand ($10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(3)(A) and (B), to the

extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

5. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

6. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, expert fees, and all attorneys' fees incurred by Relator in the prosecution of this suit; and

7. That Relator be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

132. Relator requests a trial by jury on all issues so triable.

Respectfully submitted,

Robin M. Green
Richards, Elder & Green L.L.P.
3223 South Loop 289, Suite 424
Lubbock, TX 79423
Tel. (806)798-8868
Fax. (806)798-8878
Bar # 08369000
Email: rgreen@regllp.com
Counsel for Relator

CERTIFICATE OF SERVICE

This will certify that a true copy of this Complaint was this 30th day of October, 2013, mailed via registered mail to Eric Holder, United States Attorney General, 5111 Main Justice Bldg., 10th St. & Constitution Ave., N.W., Washington, D.C. 20530, and Robert Pitman, United States Attorney for the Western District of Texas, 601 NW Loop 410, Suite 600, San Antonio, Texas 78216.

This Complaint will **not** be served on Defendants until so ORDERED by the Court.

Robin M. Green